UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

NICOLE PETTIT,	**Case No. 1:22-CV-97 (Kleeh)**
Plaintiff	
vs.	**PLAINTIFF'S COMPLAINT AND JURY DEMAND**
ANGIODYNAMICS, INC. & NAVILYST MEDICAL, INC.	
Defendants	

PLAINTIFF'S COMPLAINT AND JURY DEMAND

Plaintiff, by and through her undersigned counsel, brings this Complaint for Damages against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' implantable vascular access device ("Smartport" or "product"). As a result, Plaintiff NICOLE PETTIT suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

I. STATEMENT OF PARTIES

2. Plaintiff Nicole Pettit ("Plaintiff") is, and was, at all relevant times, a citizen and resident of West Virginia and the United States.

3. Defendant Angiodynamics, Inc. ("Angiodynamics") is a corporation organized and existing under the laws of Delaware, with its headquarters and principal place of business

located at 14 Plaza Drive, Latham, New York, 12110, and doing business within the State of West Virginia and elsewhere in the United States.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a corporation organized and existing under the laws of Delaware, with its headquarters and principal place of business at 26 Forest Street, Marlborough, Massachusetts, 01752. Angiodynamics completed a purchase of Navilyst in 2012, expanding the former's share of the market for vascular access devices.

5. Defendant Angiodynamics and Defendant Navilyst are referred to in the collective, at times herein, as "Defendants."

II. JURISDICTION

6. The Court has subject matter and personal jurisdiction over the issues and the parties to this cause of action. Defendants have conducted business and derived substantial revenue from within the State of West Virginia and have sufficient minimum contacts and intentionally avails themselves of the West Virginia market so as to render the exercise of jurisdiction over Defendants by the West Virginia courts consistent with traditional notions of fair play and substantial justice.

7. Defendants, with respect to the product at issue in the case at bar, have made or performed contracts or promises substantially connected to the State of West Virginia.

8. This court may exercise jurisdiction over Defendants under the laws of West Virginia, the West Virginia Constitution, and the Constitution of the United States.

9. Venue is proper in this Court as a substantial part of the counts giving rise to this Complaint occurred in West Virginia.

10. Plaintiff brings this complaint solely under state law and not under federal law and specifically not under the United States Constitution, or any of its amendments. Plaintiff believes and alleges that causes of action exist under the hereinafter set out state law claims for the conduct complained of herein.

III. STATEMENT OF FACTS

11. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Vascular Access Devices in the stream of commerce, including the SmartPort CT product that is at issue in this lawsuit.

12. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

13. At all relevant times, each of the Defendant, was and still is a corporation authorized to do business in the State of West Virginia.

14. At all times hereinafter mentioned, upon information and belief, Defendants were and still are business entities actually doing business in the State of West Virginia.

15. At all times hereinafter mentioned, Defendants were engaged in the business of designing, manufacturing, advertising, marketing, and selling Vascular Access Devices including the SmartPort CT Injectable Port (referred to herein, at times as "SmartPort"), and in pursuit of this business, transacted business within the State of West Virginia and contracted to provide goods and services in the State of West Virginia.

16. At all times hereinafter mentioned, upon information and belief, Defendant committed tortious acts inside the State of West Virginia, which caused injury to Plaintiff.

17. At all times hereinafter mentioned, upon information and belief, Defendants expected or should reasonably expect its acts to have consequences in the State of West Virginia.

A. DEFENDANTS' SMARTPORT VASCULAR ACCESS DEVICE

15. In or about 2010, Defendants received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell SmartPort.

16. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

17. The SmartPort is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

18. According to Defendants, the SmartPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

19. The intended purpose of the SmartPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

20. The SmartPort is a system consisting of two primary components: an injection port and a silicone catheter.

21. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

22. The SmartPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."

23. According to Defendants' marketing materials, the Fluoromax^{tm} Catheter is a high-radiopacity catheter made from 100% silicone.

24. The catheter is joined to the body of the injection port by a connection sleeve.

25. The connection sleeve is improperly designed in relation to the step of the port body due to, *inter alia*, a mismatch of the diameter of the connection sleeve to those of the catheter and port stem.

26. This sizing mismatch and lack of a functional locking mechanism creates the risk of catheter separation from the port while implanted in the patient.

27. When a catheter separates from the port, chemotherapy drugs are released in direct contact with subcutaneous and subdermal tissues, a complication known as extravasation.

28. Because chemotherapy drugs are known to be cytotoxic, extravasation causes profound damage to the aforementioned tissues to which it is exposed, prepitating severe pain, tissue necrosis, and subsequent surgical intervention.

29. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

30. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

33. In *Medtronic, Inc.* v. Lohr, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

34. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

35. At all times relevant, Defendants misrepresented the safety of the SmartPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the SmartPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

36. At all times relevant to this action, Defendants knew and had reason to know, that the SmartPort was not safe for the patients for whom they were prescribed and implanted, because

once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

37. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with SmartPorts had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

38. Soon after the SmartPort was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the SmartPort was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that SmartPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.

b. cardiac/pericardial tamponade;

c. cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. severe and persistent pain;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

39. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products – including the product implanted in Plaintiff – which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

40. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient

advocacy groups.[1]

41. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of catheter fracture – under the ASR exemption, thereby concealing them from physicians and patients.

42. Defendants were aware or should have been aware that the SmartPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

43. Defendants also intentionally concealed the severity of complications caused by the SmartPort and the likelihood of these events occurring.

44. Rather than alter the design of the SmartPort to make it safer or adequately warn physicians of the dangers associated with the SmartPort, Defendants continued to actively and aggressively market the SmartPort as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

45. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the SmartPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the SmartPort System from the market.

B. PLAINTIFF-SPECIFIC FACTUAL BACKGROUND

[1] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

46. On October 19, 2018, Plaintiff underwent placement of an implantable vascular access device at Fairmont Regional Medical Center in Fairmont, West Virginia, where she was implanted with an AngioDynamics Smart Port, Ref # CT80STPD-VI, Lot # 5378436.

47. Defendant manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for delivery of chemotherapy.

48. On February 13, 2019, at a routine chemotherapy session at United Hospital Center in Bridgeport, West Virginia, nurses initiated a saline flush prior to the administration of her Doxorubicin chemotherapy; immediately it was noticed that there was infiltration of the saline, which began leaking from her chest. She was sent for a chest X-ray and evaluation of the port with angiogram and superior vena cava venogram, which demonstrated that the left-sided port had become completely disconnected from the catheter tubing. She underwent placement of a PICC line in her left arm by Dr. John Adeniyi, M.D., and recommended to have her port removed.

49. On February 19, 2019, Plaintiff underwent surgery at Fairmont Regional Medical Center to remove the SmartPort and catheter, performed by Dr. Charles Frank, M.D. During said procedure, Dr. Frank observed that the blue hub, as well as the catheter, was completely off the injection port. He then removed the port and passed it off the field to be returned to the manufactures to see if they could ascertain why it had become unattached.

50. At all times, the SmartPort was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the product.

51. The SmartPort implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

52. Plaintiff and her physicians foreseeably used and implanted the SmartPort, and did not misuse, or alter the SmartPort in an unforeseeable manner.

53. Defendants advertised, promoted, marketed, sold, and distributed the SmartPort as a safe medical device when Defendant knew or should have known the SmartPort was not safe for its intended purposes and that the product could cause serious medical problems.

54. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

55. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the SmartPort.

56. As a result of having the SmartPort implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

57. Defendants' SmartPort was marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Vascular Access Devices.

58. The Defendants have marketed and sold the Defendants' SmartPort to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

59. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

60. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

61. Plaintiff did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

62. Defendants were negligent toward Plaintiff in the following respects:

a) Defendant failed to correct a known design defect which exposed patients to unreasonable risk of harm;
b) Defendant failed to adequately test the SmartPort, allowing defective devices to be placed in the stream of commerce;
c) Defendant failed to design and establish a safe, effective procedure for removal of SmartPort; therefore, in the event of a failure, injury, or complications it is difficult to safely remove SmartPort.
d) Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using SmartPort for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

63. The SmartPort was utilized and implanted in a manner foreseeable to Defendants.

64. The SmartPort implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

65. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with SmartPort.

66. Plaintiff was never informed by Defendants of the defective and dangerous nature of SmartPort.

67. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of SmartPort.

68. In 2019, Plaintiff did not know that the surgery she underwent was due to a defect in these products.

69. It was not until a time within the applicable statute of limitations, that Plaintiff discovered Defendants' wrongful conduct. Furthermore, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including but not limited to, the defective design and/or manufacturing of these devices until a date within the statute of limitations. Therefore,

under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

70. Plaintiff has suffered and will continue to suffer physical pain and mental anguish.

71. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in her body.

IV. STATEMENT OF CLAIM

COUNT I: NEGLIGENCE

72. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

73. At all relevant times, Defendant had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' SmartPort, and recruitment and training of physicians to implant the SmartPort.

74. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the SmartPort.

75. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the SmartPort.

76. As a direct and proximate result of the duties breached, the SmartPort failed, resulting in much pain and suffering, mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

77. As a direct and proximate result of Defendant's negligence, Plaintiff suffered severe pain, injuries and damages.

78. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered and will continue to suffer great pain and mental anguish.

79. Defendant's conduct in continuing to market, sell and distribute the SmartPort after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

80. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the SmartPort would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with SmartPort.

81. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the SmartPort, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

82. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

83. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

84. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted into Plaintiff. The product was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant. A reasonably prudent medical device manufacturer would not have placed the SmartPort with its defective design into the stream of commerce.

85. The SmartPort was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

86. The SmartPort was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physician would expect when the product was used for its normal and intended purpose.

87. The SmartPort reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

88. The SmartPort failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the SmartPort outweigh its benefits. The design defects in the SmartPort were not known, knowable and/or reasonably apparent to

Plaintiff and/or her physician or discoverable upon any reasonable examination. The SmartPort was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

89. The defective and unreasonably dangerous condition of the SmartPort was the proximate cause of the damages and injuries complained of by Plaintiff.

90. As a direct and proximate result of the SmartPort's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

91. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

92. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

93. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted in Plaintiff. The SmartPort was defective in its manufacture and construction when it left the hands of Defendant in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as

would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

94. The SmartPort as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

95. The SmartPort was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

96. The manufacturing defect in the SmartPort implanted in Plaintiff was not known, knowable or readily apparent to Plaintiff's physician or to Plaintiff. Nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The SmartPort was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

97. The SmartPort implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

98. The defective and unreasonably dangerous condition of the SmartPort product was a proximate cause of damages and injuries suffered by Plaintiff.

99. As a direct and proximate result of the SmartPort's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

100. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

101. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

102. Defendant manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their SmartPort vascular access device.

103. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that SmartPort was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and her treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive SmartPort.

104. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician as to the risks and benefits of the Defendants' SmartPort. To the contrary, Defendants withheld information from Plaintiff and her treating physician regarding the true risks as relates to implantation of their SmartPort.

105. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that inadequate research and testing of the SmartPort was done prior to

SmartPort being placed on the market and in the stream of commerce and that Defendants lacked a safe, effective procedure for removal of the SmartPort once complications from same arise.

106. The Defendant intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of SmartPort, understating the risks and exaggerating the benefits in order to advance its own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

107. The dangerous and defective conditions in the SmartPort existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had her implant surgery, the SmartPort was in the same condition as when manufactured, distributed and sold.

108. Plaintiff did not know at the time of surgery that the SmartPort placed during Plaintiff's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the SmartPort.

109. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the SmartPort, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

110. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT V: BREACH OF EXPRESS WARRANTY

111. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

112. At all relevant and material times, Defendant manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce SmartPort.

113. In advertising, marketing and otherwise promoting SmartPort to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their SmartPort was safe for use. In advertising, marketing and otherwise promoting SmartPort, Defendant intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use SmartPort for their patients.

114. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' Vascular Access Devices within the meaning of Massachusetts General Laws ch. 106, §2-3l8, as the Defendant specifically designed the SmartPort for implantation in patients requiring repeated vascular access such as Plaintiff.

115. With respect to Plaintiff, Defendant intended that SmartPort be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

116. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that SmartPort was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other Vascular Access Devices, that

it was adequately researched and tested and was fit for its intended use. Plaintiff and her physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' SmartPort.

117. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the SmartPort implanted in Plaintiff including the following particulars:

a) Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SmartPort was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SmartPort;

b) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SmartPort.

119. At the time of making such express warranties, Defendants knew or should have known that Defendants' SmartPort does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

120. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

121. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

122. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Defendants' SmartPort.

123. At all relevant times, Defendants intended that its SmartPort be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendant and Defendant impliedly warranted that their SmartPort was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

124. When the SmartPort was distributed into the stream of commerce and sold by Defendant, they were unsafe for their intended use, and not of merchantable quality, as warranted

by Defendant, in that they had very dangerous propensities when used as intended and implanted into a patient's body and, as a result, could cause serious injury of harm or death to the end user.

125. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' Vascular Access Devices within the meaning of Massachusetts General Laws ch. 106, §2-3l8, as the Defendant specifically designed the SmartPort for implantation in patients requiring repeated vascular access such as Plaintiff.

126. Defendant was aware that consumers such as Plaintiff would be implanted with SmartPort by their treating physicians in accordance with the instructions for use and product specifications provided by Defendant to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' SmartPort, and plaintiff was in privity with Defendants.

127. Defendants breached implied warranties with respect to the SmartPort including the following particulars:

a) Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' SmartPort was of merchantable quality and safe when used for its intended purpose meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SmartPort;

b) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendant fraudulently concealed information, which demonstrated that the SmartPort was not safe, as safe as or safer than alternatives and other products available on the market; and

c) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort were more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SmartPort.

128. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used SmartPort to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

129. Defendants breached their implied warranty to Plaintiff in that the Defendants' SmartPort was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

130. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendant. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

131. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

132. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

133. The acts and omissions of Defendant as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

134. The acts and omissions of Defendant, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: UNJUST ENRICHMENT

135. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

136. Defendant at all times was the manufacturer, seller, and/or supplier of SmartPort.

137. Plaintiff was implanted with Defendants' SmartPort for the purpose of treatment of ovarian cancer, and Defendants were paid for Plaintiffs use of said product.

138. Defendant have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the SmartPort with which Plaintiff was implanted.

139. Plaintiff was not implanted with nor did she receive the medical device that Defendants' represented and warranted to be safe, effective and efficacious and for which Plaintiff paid.

140. Equity demands that Defendant be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendant on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendants' conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VICARIOUS LIABILITY

141. Whenever in this complaint it is alleged that Defendant did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATION

142. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with SmartPort.

143. As a result of the Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

144. Furthermore, Defendants are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of SmartPort. Defendant had a duty to disclose the true character, quality and nature of SmartPort because this was non-public information over which Defendant had and continued to have exclusive control, and because Defendant knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. Defendant is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

145. The Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendant, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendant and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Reasonable attorneys' fees as provided by law;

iii. The costs of these proceedings, including past a future cost of the suit incurred herein;

iv. Prejudgment interest on all damages as is allowed by law;

v. Such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

NICOLE PETTIT,

Plaintiff,

By counsel:

/s/ Jason P. Foster
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